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Dr. C. W. Jameson
National Toxicology Program
Report on Carcinogens, MD-EC-14
Post Office Box 12233
Research Triangle Park, North Carolina 27709

Re: Proposed Reclassification of Nickel Compounds -- Ninth Report on Carcinogens

Dear Dr. Jameson:

We are responding on behalf of the Specialty Steel Industry of North America ("SSINA") to the February 3, 1998 notice calling for public comments on the proposed change in classification of "nickel and nickel compounds" in the National Toxicology Program ("NTP") *Ninth Annual Report on Carcinogens*. 63 Fed. Reg. 5565 (Feb. 3, 1998). Currently, the NTP lists nickel and certain nickel compounds as "reasonably anticipated to be carcinogenic." The notice announces NTP's intent to change this classification to a category of substances that are "known to be human carcinogens." SSINA believes that the proposed reclassification is unnecessary, unjustified and entirely inappropriate.

SSINA is a national trade association comprised of 19 producers of specialty steel products, including stainless, electric, tool, magnetic and other alloy steels. SSINA member companies account for over 90 percent of the specialty steel manufactured in the United States, and are geographically disbursed with sixteen located in the United States, two in Canada and one in Mexico. As major producers and users of stainless steel and other alloys that contain nickel and other elements, SSINA is interested in the proper characterization of these substances for potential regulatory purposes. In particular, SSINA is concerned about the proposed classification of nickel because nickel is a significant alloying agent in the production of many stainless steels and other high performance alloys.

As discussed more fully in the comments submitted by Wilmer, Cutler & Pickering on behalf of the Nickel Development Institute ("NiDI") and the Nickel Producers Environmental Research Association ("NiPERA"), NTP's proposal to list the entire category of nickel and nickel compounds sweeps far too broadly and ignores critical decision factors such as speciation and bioavailability. Because each species or compound of nickel may have significantly different chemical and physiological properties, each must be separately evaluated for its carcinogenic potential. For example, ferro-nickel compounds found in stainless steels are most certainly not bioavailable and could not, consistent with current epidemiology and toxicology literature, be considered carcinogens. The proposed change in classification would ignore the fact that these nickel compounds in stainless steel are universally recognized as being safe for use in a wide variety of consumer products, including cookware, eating utensils, kitchen and restaurant equipment, surgical implants, *etc.* Any proposal that would classify these benign nickel alloys as carcinogens would be entirely improper. The impact of such a gross misclassification upon the stainless steel industry could be devastating.

In their comments on the proposed classification, NiDI and NiPERA discussed the current epidemiology and other toxicology data regarding nickel carcinogenicity. The data simply do not support the classification of all forms of nickel as carcinogenic. NTP should not proceed with the proposed generic reclassification that ignores the chemical form of nickel and the specific biokinetic properties and exposure potential of each nickel compound.

SSINA supports the NiDI-INCO recommendations that under NTP's revised criteria, nickel oxide and other insoluble nickel compounds be listed no higher than "reasonably anticipated to be a human carcinogen." In fact, the results of the Redmond Study on 31,000 high nickel alloy workers suggest that this level of classification is too high. *See* Redmond, C., N. Sussman, V. Arena & J. Costantino *Supplemental Analysis of High Nickel Alloy Workers* (Final Report December 15, 1996 ("Redmond Study")). Other soluble nickel compounds (except nickel subsulfide) and metallic/elemental nickel should not be listed at all.

Sincerely,

John L. Wittenborn